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# Value-Driven Partnerships Leading the Shift to Value-Based Care

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Healthcare spending in the United States continues to soar, topping out at \$3.5 trillion in 2017.<sup>1</sup> A substantial proportion of that (\$327 billion) encompassed spending on diabetes care, including approximately \$37 billion for cardiovascular (CV) healthcare costs associated with diabetes.<sup>2</sup> Cardiovascular disease (CVD), including atherosclerosis, stroke, myocardial infarction, and heart failure, is the leading cause of death among adult patients with type 2 diabetes (T2D), with their risk of dying from a CVD-related event being 3 times higher than for an adult patient without T2D.<sup>3</sup> Furthermore, patients with T2D who die due to CV events utilize 2- to 6-fold more healthcare resources in their final months of life compared with patients with T2D who die of other causes.<sup>4</sup> The results of a 2016 analysis of all-cause costs relating to T2D and its complications demonstrate that 45% of healthcare resources go toward treatment of T2D, 28% to treatment of complications of CVD, 15% to management of renal complications, 6% to neurologic complications, and 6% to ophthalmic complications.<sup>5</sup>

Improvement in the clinical and economic management of patients with comorbid T2D and CVD remains a significant unmet need. Value-based care programs that focus on the total cost of care of these individuals and the value of the care provided are one way to address this need. Multiple strategies exist to move toward value-based care; examples include provider-facing initiatives such as accountable care organizations and reference pricing, as well as patient-facing programs such as value-based insurance design.<sup>6</sup> Aligning clinician and provider incentives is critical to improving patient-centered outcomes and efficiency in the delivery of care.

Value-based care programs require partnering organizations—and their healthcare providers and patients—to think differently about

addressing unmet needs in disease management, both clinically and economically. These programs are shifting the focus to therapeutic options and care programs that will bring the highest return on investment in terms of cost of care and patient-centered outcomes. For example, value-based care for chronic conditions, such as diabetes, must go beyond management of glycated hemoglobin levels.

To improve patient health and possibly reduce total cost of care for patients with T2D and established CV disease, value-based care models should prioritize measurement of hospital admissions due to MI, stroke, or HF. Two drug classes with proven CV benefit—sodium-glucose cotransporter 2 (SGLT-2) inhibitors and glucagon-like peptide 1 receptor agonists—have demonstrated potential to help meet these goals in patients with comorbid T2D and CVD. These agents impart significant reductions in major adverse CV events. And, although not indicated, both classes of agents have additional nonglycemic benefits, including systolic blood pressure reduction and weight reduction.<sup>7</sup>

These agents make it possible to improve the management of adult patients with T2D and established CVD. The American College of Cardiology and the American Diabetes Association recognize the CV benefits of these agents and have updated their guidelines to recommend them in concert with first-line agents for patients with comorbid CVD and T2D, when indicated.<sup>7,8</sup> This inclusion further reinforces the importance of CVD risk management in diabetes care and sets the stage for innovative value-driven partnerships that capitalize on these recommendations to decrease total cost of care and increase positive patient outcomes. Boehringer Ingelheim is the first organization to pursue these innovative value-driven partnerships based on CV outcomes and total cost of care. •

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THE AMERICAN JOURNAL OF MANAGED CARE

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# Boehringer Ingelheim and UPMC Health Plan: A Value-Driven Partnership Focused on Outcomes in Diabetes and Cardiovascular Disease

Editors from *The American Journal of Managed Care*<sup>®</sup> sat down with 2 executives from the University of Pittsburgh Medical Center (UPMC) Health Plan: Chronis Manolis, RPh, chief pharmacy officer, and senior vice president of pharmacy, and Chester “Bernie” Good, MD, MPH, senior medical director at the plan’s Center for Value Based Pharmacy Initiatives. The focus was UPMC Health Plan’s experience in creating a value-driven partnership (VDP) with Boehringer Ingelheim centered around Jardiance<sup>®</sup> (empagliflozin) tablets, a sodium-glucose cotransporter 2 (SGLT-2) inhibitor

for type 2 diabetes (T2D), which was shown in the EMPA-REG OUTCOME trial to reduce the risk of cardiovascular death in adults with T2D and established cardiovascular disease (CVD).<sup>1</sup> The interview focused on UPMC Health Plan’s experiences in creating and managing the VDP, including the plan’s rationale for participation, areas of focus, expected benefits, and organizational challenges and solutions.

The goal of the UPMC Health Plan/Boehringer Ingelheim VDP is to enable the systemic change from volume to value that health plans in the United

## INDICATIONS AND LIMITATIONS OF USE

JARDIANCE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

JARDIANCE is indicated to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus and established CV disease.

JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

## IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS:** History of serious hypersensitivity to empagliflozin or any of the excipients in JARDIANCE, severe renal impairment, end-stage renal disease, or dialysis.

**Please see additional Important Safety Information throughout and accompanying Prescribing Information for Jardiance (empagliflozin) tablets, including Medication Guide.**

States are in a unique position to drive for their clients, employers, providers, and their communities. Underlying development of VDPs is the belief that the use of products with robust clinical trial evidence, such as JARDIANCE, translates into better outcomes for appropriate patient populations who use these products, and those outcomes will translate into total cost-of-care savings. UPMC Health Plan/Boehringer Ingelheim’s innovative value-based contract centered around JARDIANCE has demonstrated an annual total cost-of-care savings of \$13,704 per patient per year, primarily driven by a reduction of up to 50% in medical costs across all sites of care (see **Figure**).<sup>2</sup> If, at the end of their contract period, UPMC Health Plan does not realize a total cost-of-care savings after utilizing JARDIANCE in the appropriate patient population, compared with another T2D treatment, then Boehringer Ingelheim will retrospectively adjust the net price accordingly.

Boehringer Ingelheim is dedicated to ensuring that JARDIANCE and their other approved products supported by robust clinical evidence and meaningful economic outcomes are accessible to those who would benefit from their use. Partnering with organizations like UPMC Health Plan offers a way to do so while continuing Boehringer Ingelheim’s larger commitment to innovating life-changing advances in medicine. A focus on total cost-of-care savings places Boehringer Ingelheim on the cutting edge of innovation as healthcare evolves from volume to value.

UPMC Health Plan is among the nation’s fastest-growing health plans and is owned and operated by the University of Pittsburgh Medical Center, a world-renowned healthcare provider. UPMC Health Plan partners with UPMC providers and community network providers to produce a combination of knowledge and expertise that provides the highest quality care at the most affordable price. The UPMC Insurance Services Division—which includes UPMC Health Plan, WorkPartners, UPMC for Life, UPMC for You, UPMC for Kids, Community Care Behavioral Health, and others—offers a full range of group health insurance, Medicare, Special Needs Plan, CHIP, Medical Assistance, behavioral health, employee assistance, and workers’ compensation products and services to more than 3.5 million members. Their local provider network includes UPMC providers as well as community providers, totaling more than 140 hospitals and more than 29,000 physicians throughout Pennsylvania and parts of Ohio, West Virginia, and Maryland.

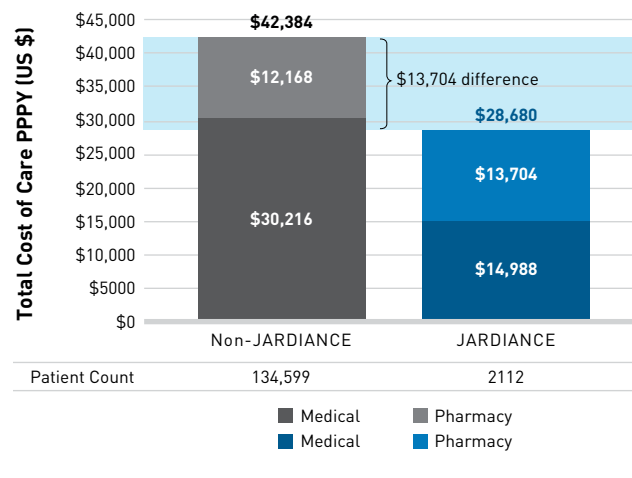
The interview with Manolis and Good appears next.

**AJMC®: What does “value” mean to UPMC Health Plan?**

**Manolis:** Value means enhancing the benefits for our members by decreasing cost, or without increasing cost. There are many challenges in the current pharmacy environment. One challenge is that we still pay our pharmacies based on a fee-for-service methodology, and that reimbursement framework largely ignores the clinical expertise of the pharmacist and the relationship a pharmacist has with patients during face-to-face encounters. The industry has been slow to move to value-based reimbursement in the retail pharmacy environment, and for the most part, that is where the rubber hits the road; that is where a lot of these prescriptions get dispensed and where the clinical opportunity lies.

Conversely, the medical side of the house has been moving to value-based reimbursement. There are variations of “pay-for-performance” programs, as well as shared savings and shared risk methodology; however, we want drugs [as well as services] to be included in those models because we want physicians who are

**Figure.** Expected Outcomes and Annual Total Cost-of-Care Savings of Boehringer Ingelheim Value-Based Contract<sup>2</sup>



PPPY indicates per patient per year.

**IMPORTANT SAFETY INFORMATION (CONTINUED)  
WARNINGS AND PRECAUTIONS**

**Hypotension:** Empagliflozin causes intravascular volume contraction and symptomatic hypotension may occur. Before initiating JARDIANCE, assess and correct volume status in the elderly, and in patients with renal impairment, low systolic blood pressure, or on diuretics. Monitor for hypotension.

**Ketoacidosis:** Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been identified in patients with type 1 and type 2 diabetes mellitus receiving SGLT2 inhibitors, including empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking empagliflozin. Patients who present with signs and symptoms of metabolic acidosis should be assessed for ketoacidosis, even if blood glucose levels are less than 250 mg/dL. If suspected, discontinue JARDIANCE, evaluate, and treat promptly. Before initiating JARDIANCE, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation in situations known to predispose to ketoacidosis. For patients who undergo scheduled surgery, consider temporarily discontinuing JARDIANCE for at least 3 days prior to surgery.

**We want to link the price that we pay for a drug with the outcomes that drug produces, introducing more accountability and more risk for all stakeholders.**

prescribing to be aware of the cost of drugs and the value of those products. Currently, physicians do not always think about costs and what the patient is going to pay, and so the patient may be confused or frustrated by prescription costs.

Finally, there are drug rebates. Rebates have traditionally been negotiated solely based on formulary positioning and market share or volume. If a drug can get preferred positioning on a formulary, the plan gets reimbursed for that. At UPMC Health Plan, we want to move to more accountability in rebate contracting. We want to link the price that we pay for a drug with the outcomes that drug produces, introducing more accountability and more risk for all the stakeholders.

**Good:** I would add to that when looking at “value,” defined as benefit divided by cost, we have tried to determine what “benefit” refers to and broaden our thinking about what encompasses a benefit. We are doing this by focusing on patient outcomes that matter. For example, patient outcomes such as decreased admissions for a heart attack or a stroke are important; however, other outcomes that are not as readily apparent, such as being able to continue working while being treated for a disease, are also important. As such, we are trying to take a holistic approach to the definition of value and take these other benefits into consideration.

Furthermore, we are working to expand our definition of “cost” to include not just pharmacy and drug cost, but also total cost of care.

**AJMC®: Why does UPMC Health Plan believe in value-based care?**

**Good:** UPMC Health Plan is part of one of the largest integrated delivery and finance systems in the country, which allows us to consider everything in terms of that value metric that we just discussed. If we focus on aspects that offer the most value, it becomes a classic

win-win situation. Patients in UPMC Health Plan win because they experience better outcomes, and we win because our cost of care and outcomes are better.

**Manolis:** It is well documented that outcomes are not commensurate with healthcare costs in the United States. The cost of healthcare in the United States is skyrocketing and is consuming an ever-larger share of our gross domestic product. I am not sure how we can circumvent these challenges if we do not change from a fee-for-service model to a value-based reimbursement model where all the stakeholders are accountable and all the incentives are aligned.

For example, the first \$2-million gene therapy was just approved. Gene therapies such as these are going to be transformative; they are going to change people’s lives. However, we need to ensure access to them and their affordability. It’s imperative that our methodologies are rooted in value and that we are driving toward the highest quality and the most efficiency to meet the Quadruple Aim<sup>3</sup> standard.

**AJMC®: What are some interventions that UPMC Health Plan is using to promote value and to drive value-based outcomes?**

**Manolis:** The value-based reimbursement construct is critical. We are working to align incentives, ensuring that, first and foremost, the quality of care is high, and that the care model is developed through a value- and evidence-driven pathway. We are rapidly moving in that direction with our provider partners—both medical and pharmacy—because that value-based framework is imperative for higher quality patient care.

UPMC Health Plan, which is part of a system that includes a nationally recognized health system and an academic medical center, provides a unique ecosystem and platform. By integrating all stakeholders, our ecosystem is focused on supporting the whole patient, [utilizing] team-based care where everyone has a patient-centered view that aligns with the incentives. Our value-based reimbursement models, our ability to evaluate interventions through the UPMC Center for High Value Healthcare, dissemination of that research, and our data analytics assets all work together to drive our evolution from a fee-for-service to a value-based reimbursement world. Furthermore, our UPMC Center for Value-Based Pharmacy Initiatives is helping to leverage these tools to develop an innovative value-based approach to medications.

## **IMPORTANT SAFETY INFORMATION (CONTINUED) WARNINGS AND PRECAUTIONS (CONTINUED)**

**Acute Kidney Injury and Impairment in Renal Function:** Empagliflozin causes intravascular volume contraction and can cause renal impairment. Acute kidney injury requiring hospitalization and dialysis has been identified in patients taking SGLT2 inhibitors, including empagliflozin; some reports involved patients younger than 65 years of age. Before initiating JARDIANCE, consider factors that may predispose patients to acute kidney injury. Consider temporary discontinuation in settings of reduced oral intake or fluid losses. Monitor patients for signs and symptoms of acute kidney injury. If it occurs, discontinue JARDIANCE and treat promptly.

Empagliflozin increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Before initiating JARDIANCE, evaluate renal function and monitor thereafter. More frequent monitoring is recommended in patients with eGFR <60 mL/min/1.73 m<sup>2</sup>. Discontinue JARDIANCE in patients with a persistent eGFR <45 mL/min/1.73 m<sup>2</sup>.

**AJMC<sup>®</sup>: How are you incentivizing the different stakeholders in the game, such as the internal providers, to want to participate in such a model?**

**Manolis:** UPMC Health Plan's providers include both UPMC and non-UPMC providers; however, our programs promote similar value-based reimbursement models depending on practice size and other variables. The value-based provider program requires adherence to quality parameters as well as financial incentives to achieve more cost-effective care. There is continued work to align physician incentives with the ways their other reimbursements are structured to enhance their focus on value rather than volume

**AJMC<sup>®</sup>: What are some of the gaps in therapy that UPMC Health Plan targets in the population of patients with type 2 diabetes and CVD?**

UPMC Health Plan values healthcare technologies (including pharmaceuticals) that improve the lives of our patients through improved health. In the arena of T2D and CVD pharmacotherapy, we are interested in promoting therapeutic options that have evidence to improve clinically relevant outcomes while also minimizing costs for our patients and plan sponsors. Many medications for diabetes have seen recent escalations in costs without any corresponding increase in efficacy. We were excited to identify a VBP that encourages the use of a medication that can help us address this challenge.

**AJMC<sup>®</sup>: What led to the exploration of a collaborative value-driven partnership with Boehringer Ingelheim?**

**Manolis:** We created the UPMC Center for Value-Based Pharmacy Initiatives in 2017 to advance drug affordability and how we reimburse for medications. One of the Center's missions is to understand how our unique UPMC ecosystem can support the development of effective value-based contracting.

**Good:** Rather than wait for industry partners to come to us with a cookie-cutter value-based contract that they had developed for others, we wanted to look at the big-picture. We wanted to review all our lines of business and areas where we think we have a significant pharmaceutical cost and an opportunity to improve value. We then targeted a number of disease states.

One of the disease states that turned out to be exceedingly important to our health plan was diabetes. We then surveyed our various

stakeholders—patients, primary care providers, endocrinologists, pharmacy benefit managers, and industry partners—using the Delphi method to determine which outcomes were important for this disease state.

We then reviewed an epidemiologic study of various outcomes associated with different diabetes medication types and determined which medication might be an ideal candidate, which, in this case, was Jardiance<sup>®</sup> (empagliflozin) tablets.

As a result, we realized there was opportunity to leverage our interest in this evidence-based medicine, and so we approached Boehringer Ingelheim regarding a VDP and they were very interested. They were an excellent industry partner with us throughout the process, and we are proud of the value-based contracting that we co-developed.

In this contract, we are not just focusing on patients with established CVD, but all patients within UPMC Health Plan, which is exciting. That is an interesting value proposition for patients taking JARDIANCE.

**AJMC<sup>®</sup>: How did UPMC Health Plan operationalize internally to formally enter into this contract?**

**Manolis:** We spoke with our endocrinologists, cardiologists, and family practice providers to gain their thoughts on moving to exclusive JARDIANCE status, since the move could disrupt many patients who were on a different product. We reached a clinical consensus and then began mapping out our implementation strategy. This involved discussions with our line-of-business owners, member services, clinical leaders, marketing, and our network providers (pharmacies and physicians) to create a comprehensive communication campaign to explain the change.

The multilayered communication plan consisted of phone calls, formulary change letters, and multiple in-person communications with all stakeholders. It has been a rather seamless experience because we had all the stakeholders on board from the beginning.

**Good:** I would add that again, these actions directly connect back to our philosophy of focusing on drugs that will make a difference to our patients. If we were trying to enter into a contract with a medication that did not have robust positive outcomes, it would have been a much harder sell.

We went to great lengths to meet with our subject matter experts and the “boots-on-the-ground” people to make sure that everyone

## IMPORTANT SAFETY INFORMATION (CONTINUED) WARNINGS AND PRECAUTIONS (CONTINUED)

**Urosepsis and Pyelonephritis:** Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in patients receiving SGLT2 inhibitors, including empagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate for signs and symptoms of urinary tract infections and treat promptly.

**Hypoglycemia: The use of JARDIANCE in combination with insulin or insulin secretagogues** can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required.

**Necrotizing Fasciitis of the Perineum (Fournier's Gangrene):** Serious, life-threatening cases requiring urgent surgical intervention have occurred in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue JARDIANCE.

“As more organizations demand that clinically relevant outcomes are tied into these contracts, more pharmaceutical companies will create these contracts.”

was comfortable with the contract. If our subject matter experts told us that they did not agree with using this drug in this way, we would have had to step back and start from scratch.

**AJMC®: Did you experience any internal push-back in terms of sending UPMC Health Plan data to Boehringer Ingelheim to fulfill the contract requirements?**

**Manolis:** No. First and foremost, the data are deidentified and aggregated, so Boehringer Ingelheim is not receiving any identifiable patient-level data. We are experienced with rebate administration, and so we understand the requirements around privacy.

**Good:** Internally, we have a robust data analytics group through which we are able to pull and share deidentified data in a way that is organizationally compliant.

**AJMC®: Were Jardiance® (empagliflozin) tablets already on the formulary?**

**Good:** Yes, JARDIANCE was a preferred agent on formulary, but it was not the only SGLT-2. As part of the value-based contract, we moved JARDIANCE to exclusive status, although exclusivity was not the impetus for the contract. The value-based contract is measuring total cost of care; it is outside of our pharmacy benefit manager's (PMB) purview.

**AJMC®: Other organizations may have to work with a PBM to enter into such a contract. What advice would you have for them?**

**Good:** If the PBM does the rebate negotiation, then the organization will have to have a discussion regarding the formulary change in terms of going from two SGLT-2 inhibitors on formulary to one. The PBM and organization need to discuss the ramifications in terms of

cost, but that is separate from a value-based contract. A value-based contract that measures medical outcomes or total costs of care is generally outside of the traditional PBM relationship.

Depending on the PBM contract, however, certain health plans may not be allowed to discuss this on their own with the manufacturer.

**AJMC®: Can you describe some of the projects that UPMC Health Plan and Boehringer Ingelheim have engaged in as a result of the value-driven partnership?**

**Manolis:** We continue to meet periodically, and it is certainly a wonderful partnership. It has opened the door to other conversations around other products because it has been such a successful and innovative partnership.

Boehringer Ingelheim was one of the first organizations that would do a total-cost-of-care contract, particularly in this space, and it is a contract that we are going to learn from.

**AJMC®: What most excited UPMC Health Plan about this contract with Boehringer Ingelheim?**

**Manolis:** Our goal is to put more accountability on the manufacturer, and so, instead of just getting paid for formulary positioning, we are getting paid for a combination of formulary positioning and outcomes. There is a commitment from us to move people to JARDIANCE. We think it is the right drug for our members, and so, our pharmacy costs could very well increase, but our medical costs and total costs should decrease. If they do not, there is a financial consequence for Boehringer Ingelheim.

Our care model is going to help patients stay adherent to drugs, and make sure their drug regimens are optimized. That is good for our members, and it is good for Boehringer Ingelheim as more people will get access to their product.

**Good:** We are building a portfolio of value-based contracts that we think are looking at clinically relevant outcomes as well as outcomes that are important to patients. This contract with Boehringer Ingelheim is one of our earliest ventures, and it has set the tone for other potential industry partners.

**AJMC®: Do you have results that you are able to share, yet?**

**Good:** It is still too early to share results. We are reviewing outcomes from different angles, and it is going to be exciting when those data

## IMPORTANT SAFETY INFORMATION (CONTINUED) WARNINGS AND PRECAUTIONS (CONTINUED)

**Genital Mycotic Infections:** Empagliflozin increases the risk for genital mycotic infections, especially in patients with prior infections. Monitor and treat as appropriate.

**Hypersensitivity Reactions:** Serious hypersensitivity reactions have occurred with JARDIANCE (angioedema). If hypersensitivity reactions occur, discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve.

**Increased Low-Density Lipoprotein Cholesterol (LDL-C):** Monitor and treat as appropriate.

**MOST COMMON ADVERSE REACTIONS (≥5%):** Urinary tract infections and female genital mycotic infections.

**DRUG INTERACTIONS:** Coadministration with diuretics may enhance the potential for volume depletion.

are available to share. For example, we are studying data on individuals who switched from one SGLT-2 to another, as well as those who were on different drugs and then switched to JARDIANCE. We are excited to learn what those outcomes are going to be.

**Manolis:** It is important to note that medical claims have a completion rate period associated with them, and so we really only have about 3 months of solid data. We will need a longer period of time for outcomes evaluation.

**AJMC®: What advice would you give to other organizations that are looking to enter into a value-driven partnership?**

**Manolis:** UPMC Health Plan has a strong advantage because the collaboration with its providers is a seamless and collegial process. Other payers may not have the same type of relationship with their providers; they may have adversarial relationships, or, more likely, neutral relationships. Full consensus is not necessary to enter into this type of partnership, but the process will be seamless when you have it. When all the stakeholders have a seat at the table and are part of the decision-making process, pharmacy and policy decisions become more effective.

An [absolute] requirement is having access to all necessary data. Also, an organization needs to determine if they can aggregate all medical and pharmacy claims and associated analytic expertise. Finally, value-based contracts are sophisticated and have a large amount of inclusion criteria, exclusion criteria, etc, and not everyone may be able to manage these complex negotiations; however, it can be a win-win for the organizations involved.

**Good:** The take-home message is that it can be done, but each contract requires hard work. We hope that our positive results will encourage others to try to be innovative and to do things that matter for their patients. As more organizations demand that clinically relevant outcomes are tied into these contracts, more pharmaceutical companies will create these contracts.

**Manolis:** The process with Boehringer Ingelheim was relatively easy and that should not be ignored or understated. We were all transparent from the start in that we were looking for something innovative and that we had an ecosystem we wanted to leverage. We put all our assets on the table, and we challenged ourselves and Boehringer Ingelheim to come back with something beyond “business as usual.”

The result was a total-cost-of-care contract for all patients with T2D, not just patients with cardiovascular disease and T2D, which was truly innovative.

**AJMC®: Presuming that the contract was successful, what would a next-level VDP look like?**

**Good:** A next-level VDP could incorporate patient-reported outcomes. There are certain drugs out there where there is not going to be any return on investment when viewed from a purely administrative claims point of view. There might be more spending within a drug class, or no impact on hospitalizations or emergency department visits. But these are drugs that improve the patient’s quality of life, their ability to work, etc.

We are still going to be interested in total cost of care and various clinical outcomes because those aspects are important, but we are excited about the possibility of also including what we hear from our patients. Not every healthcare system would be able to pull that off, but UPMC Health Plan’s infrastructure and ecosystem should enable us to gather robust patient-reported outcomes and it will be an exciting opportunity to enhance value for our members. •

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**IMPORTANT SAFETY INFORMATION (CONTINUED)  
USE IN SPECIAL POPULATIONS**

**Pregnancy:** JARDIANCE is not recommended, especially during the second and third trimesters.

**Lactation:** JARDIANCE is not recommended while breastfeeding.

**Geriatric Use:** JARDIANCE is expected to have diminished efficacy in elderly patients with renal impairment. Renal function should be assessed more frequently in elderly patients. The incidence of volume depletion-related adverse reactions and urinary tract infections increased in patients ≥75 years treated with empagliflozin.

